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| 09/502,762      | 02/11/2000  | Alan P. Sliski       | PHLL-141            | 5635             |

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| EXAMINER |
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| ART UNIT | PAPER NUMBER |
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2881

DATE MAILED: 12/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/502,762

Applicant(s)

SLISKI ET AL.

Examiner

Anthony Quash

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 4 are rejected for the use of the words "adapted to". It has been held that the recitation that an element is "adapted to" to perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense.

Claims 7-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 and 15 recite the limitation "said area" in lines 7 and 9 respectively. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Nomikos [900]. As per claim 1, Nomikos [900] discloses a biocompatible radiation shield (34) for use with a radiation applicator system (10) for a radiation source, the radiation

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applicator system (10) including an applicator head (26) defining a shape having a predefined shape and surface contour, the radiation shielding comprising a substantially thin, biocompatible material (34), adapted to conform to the shape of at least a portion of the surface contour of the applicator head (26). See Nomikos [900] figs. 1-2, col. 6 lines 20-45, and col. 7 lines 19-37.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nomikos [900]. As per claim 2, Nomikos [900] teaches all aspects of the claim except for specifically stating that the biocompatible material include at least one radiation blocking or absorbing material chosen from the group including tungsten, gold, platinum, rhodium, iridium, tantalum and barium oxide. However, Nomikos [900] does teach that the biocompatible shielding can be configured of other x-ray shield materials. See Nomikos [900] col. 7 lines 30-37. It also teaches a thin film being applied to the applicator head (26) made of tungsten. See Nomikos [900] col. 6 lines 20-30. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the biocompatible material include at least one radiation blocking or absorbing material chosen from the group including tungsten, gold,

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platinum, rhodium, iridium, tantalum and barium oxide in order to shield the patient from incident electrons as taught in Nomikos [900].

As per claim 3, Nomikos [900] teaches the biocompatible material including at least one material chosen from the group including urethane, silicone, polyamides, and polystyrenes. See Nomikos [900] col. 7 lines 19-29.

As per claim 4, Nomikos [900] teaches at least a portion of the biocompatible material being adapted to be couple to the applicator head (26). See Nomikos [900] figs. 1-2, col. 6 lines 20-45, and col. 7 lines 19-37.

As per claim 5, Nomikos [900] implies that the biocompatible radiation shield is formed from tungsten filled urethane material. See Nomikos [900] figs. 1-2, col. 6 lines 20-45, and col. 7 lines 19-37. However, Nomikos [900] does not specifically state that the material include approximately 60 to 90 percent tungsten by weight. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the material include approximately 60 to 90 percent tungsten by weight, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art.

As per claim 6, Nomikos [900] implies that the biocompatible radiation shield is formed from tungsten filled urethane material. See Nomikos [900] figs. 1-2, col. 6 lines 20-45, and col. 7 lines 19-37. However, Nomikos [900] does not specifically state that the material include approximately 80 percent tungsten by weight. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the material include approximately 80 percent tungsten by weight, since it has

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been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

### ***Allowable Subject Matter***

Claims 7-20 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not disclose nor teach, "... an applicator, substantially encasing a radiating probe of the radiation source, the applicator including: a shank having a proximate end and a distal end, and a head secured to the shank distal end and defining a surface for engaging the area to receive the dose of radiation; and an adapter, including: a first coupler suited for mated engagement with the shank proximate end; and a second coupler suited for mated engagement with the radiation source; and a biocompatible radiation shield coupled to at least a portion of the head."

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent Nos. 4,968,305 to Takahashi et al ; 6,181,770 to Ciravolo et al ; 5,369,679 to Sliski et al ; 5,566,221 to Smith et al ; and 5,618,266 to Liprie ; are considered pertinent. Takahashi [305] is considered pertinent because of its teaching of a kit for the administration of a radio pharmaceutical liquids. Sliski [679] is considered pertinent because of its teaching of a low power x-ray source with implantable probe for treatment of brain tumors. Smith [221] is considered pertinent

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because of its teachings on an apparatus for applying a predetermined x-radiation flux to an interior surface of a body cavity. Ciravolo [770] is considered pertinent because of its teachings of an x-ray source interlock apparatus. Liprie [266] is considered pertinent to because of its discussion of a catheter for maneuvering radioactive source wire to site of treatment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anthony Quash whose telephone number is (703)-308-6555. The examiner can normally be reached on M-F from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John R. Lee, can be reached on (703)-308-4116. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0956.



A. Quash 12/4/02

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